REMARKS

Applicants wish to thank Examiner Fubara for granting an interview with the inventor, Joseph Artiss, and with applicant's representative, Mary Anne Schofield, on October 22, 2004. During the interview amendments to claims 13 and 80 to address the 112 issues raised in the Office Action were discussed and agreed upon. The differences between the cited reference, Suzuki et al., and the claimed invention were also discussed. Examiner Fubara agreed to consider the amendments and remarks once the response to the Office Action is filed.

THE SPECIFICATION AMENDMENTS

Applicants have amended page 33 to correct a typographical error.

THE CLAIM AMENDMENTS

Applicants have amended claim 13 to recite that the α-cyclodextrin or α-cyclodextrin complexes are not removed from the food prior to ingestion. Support for this amendment is found in, e.g., the Examples where food products are prepared and the α-cyclodextrin or α-cyclodextrin complexes are not removed prior to consumption.

Applicants have amended claim 80 to track the language of claim 77 on which it depends. As amended claim 80 recites:

> The method of claim 77 wherein said ratio of administered α-cyclodextrin to ingested fat that is in excess of the amount of fat that the subject desires to absorb is about 1:13 to about 1:5.

Applicants have amended claims 91, 92, 93 and 94 as suggested by the Examiner to improve their clarity. As amended the claims recite:

> "...α-cyclodextrin is consumed before a meal comprising a fat-containing food product or with a meal comprising a fat-containing food product."

THE REJECTION OF THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH –NON-ENABLEMENT

Claim 80 stands rejected under 35 U.S.C. 112, first paragraph for purportedly being non-enabled. While applicants respectfully disagree, applicants have amended claim 80 such that it does not recite the term "prevent." As amended claim 80 recites:

> 80. The method of claim 77 wherein said ratio of administered α-cyclodextrin to ingested fat that ~~the subject desires to prevent from being absorbed~~ is in excess of the amount of fat that the subject desires to absorb is about 1:13 to about 1:5.

In view of the amendment of the claim applicants respectfully request that the Examiner reconsider and withdraw the rejection of claim 80 for purportedly lacking enablement.

THE REJECTION UNDER 35 U.S.C. 112, SECOND PARAGRAPH - INDEFINITENESS

Claims 13-17, 62-76 and 80-81 stand rejected under 35 U.S.C. 112, second paragraph for purportedly being indefinite.

Regarding claim 13, the Examiner states that the term "α-cyclodextrin" (in last line of claim 13 which recites "said α-cyclodextrin is not removed from said food product prior to consumption") should be "α-cyclodextrin-fat complexes." Although applicants believe that the claim is clear applicants have amended claim 13 such that it recites "...α-cyclodextrin or α-cyclodextrin complexes are not removed from the food product prior to consumption."

Regarding claim 17, the Examiner during the interview agreed that upon further consideration that the unamended claim satisfies 35 U.S.C. 112, second paragraph

Regarding the rejection of claim 80 under 35 U.S.C. 112, second paragraph, the Examiner contends that claim 80 is confusing because it is not clear as to what the claim is directed to. Applicants and the Examiner discussed this claim during the interview and

applicants have amended claim 80 to improve its clarity. As amended claim 80 tracks the language of claim 77 on which it depends. In view of the amendment of claim 80 applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claim.

In view of the foregoing remarks and amendments to the claims applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. 112, second paragraph for purported indefiniteness.

THE REJECTION UNDER 35 U.S.C. 103 -OBVIOUSNESS

Those of skill in the art appreciate that food in the stomach, in the form of chyme, is slowly released into the small intestine and that almost all nutrient absorption occurs in the small intestine. Chyme is essentially a free flowing mixture of the ingested food mixed with salivary juices, stomach acids and water. Those of skill in the art also appreciate that triglycerides within the food cannot be absorbed directly through the walls of the small intestine but that free fatty acids and monoglycerides, which are released from the triglycerides by the action of lipases within the small intestine, are readily absorbed through the walls of the small intestine.

Applicants discovered that α-cyclodextrin forms very stable complexes with triglycerides in the presence of water within ratios of about 1:20 to 1:3 α-cyclodextrin:fat (see specification Figure 9A-C (alpha, beta and gamma cyclodextrin respectively, see also Tab A attached to this response). The complexes are clearly formed in tubes comprising 5% α-cyclodextrin through 25% α-cyclodextrin. At greater than 25% α-cyclodextrin and less than 5% α-cyclodextrin, one begins to observe the presence of uncomplexed oil.

Applicants disclosed that these stable complexes are resistant to lipase digestion, page 34, lines 17 to 19 (see also Tab B), which would release monglycerides and free fatty acids for absorption through the walls of the small intestine. Applicants also disclosed that the percentage of fat in the feces of rats fed the high fat diets comprising α-cyclodextrin and fat at a 1:9 ratio is increased by 25%.

Applicants compared the weight gain in rats fed a low fat diet (4% fat, 4g fat per 100g of food) and rats fed a high fat diet (40%, 40g fat per 100g of food) with or without the addition of α-cyclodextrin.

Applicants demonstrated that rats fed the high fat diet containing α-cyclodextrin, at a ratio of 1:10 α-cyclodextrin:ingested fat, gained weight at the same rate as the rats fed the low fat diet without the addition of α-cyclodextrin even though the rats fed the high fat diet were consuming 36 grams of fat more than were fed to the low fat rats (see specification Figure 3, and Tab C). The specification Figure 2 (Tab D) demonstrates that the caloric intake of rats fed the high fat diets with or without α-cyclodextrin were the same and exceeded the caloric intake of rats fed the low fat diets. Yet the rats fed the high fat plus α-cyclodextrin diet gained weight at the same rate and in the same amount as the rats fed the low fat diet without α-cyclodextrin.

Applicants' invention relates to methods for reducing the bioavailability of fat in fat-containing food products by adjusting the ratio of α-cyclodextrin and fat contained within the food product, or ingested by a subject, such that the ratios of α-cyclodextrin to fat are about 1:20 to about 1:3, thereby reducing the bioavailability of ingested fat. Such a method is not disclosed by Suzuki et al., as discussed below.

Claims 13-116 stand rejected under 35 U.S.C. 103(a) for purportedly being obvious in view of Suzuki et al. JP 6094912. (Applicants note that only claims 13-17 and 62-116 are pending in this application.) The Examiner states:

> "Suzuki discloses compositions that are administered to subjects to reduce fat and the composition comprises α-cyclodextrin present in the amounts of 10-40%. Suzuki does not determine the amount of fat contained in the food before administering the α-cyclodextrin. Regarding the forming of α-cyclodextrin -fat complex, it is inherent that a complex would form when α-cyclodextrin come in contact with fat. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to administer the composition of Suzuki to reduce fat. One of

> ordinary skill in the art would have been motivated to administer α-cyclodextrin to a subject in need thereof with the expectation of reducing fat."(emphasis added) (Office Action page 5.)

Applicants respectfully disagree and in view of the following remarks request that the Examiner reconsider and withdraw the rejection of the claims.

To support a rejection under 35 U.S.C. 103, the cited art must provide both (1) the suggestion to those of ordinary skill in the art that they should carry out the claimed process; and (2) that in carrying out the claimed process, those of ordinary skill would have a reasonable expectation of success.

> "[A] proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. . . .Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant's disclosure."
>
> *In re Vaeck*, 20 USPQ2d 1438, 1442 (CAFC 1991)

Applicants have developed a method for reducing the bioavailability of fat in a food product by mixing α-cyclodextrin into the food product to achieve the ratios of α-cyclodextrin to fat disclosed in the specification. Applicants methods also comprise determining the amount of fat ingested by a subject that is in excess of the amount of fat that the subject wishes to absorb, and then administering an appropriate amount of α-cyclodextrin such that the ratio of α-cyclodextrin to excess fat is 1:20 to about 1:3.

In contrast to Applicants' teachings, Suzuki et al. does not teach that α-cyclodextrin forms complexes with fat; rather Suzuki et al. teaches that α-cyclodextrin is a low calorie carbohydrate substitute that can be used to replace traditionally used carbohydrates such as

starches, sucrose, maltose, glucose etc. See English translation of Suzuki et al., page 6, lines 6-7, sentence spanning pages 6-7:

> The first of such effects is that of a low calorie carbohydrate, having effective actions of body weight gain suppression and body weight reduction. (Suzuki et al. page 6, lines 6-7)
>
> They can be used as a replacement at various ratios with traditionally widely used carbohydrates such as starch, processed starch, dextrin, starch syrup, starch powder, sucrose, isomerized sugar, maltose, glucose etc. (Suzuki et al., sentence spanning pages 6-7)

See also Suzuki et al. Example 2, wherein 30-50% of the wheat flour is replaced by an α-cyclodextrin composition, and Example 4 "Production of a low calorie biscuit", and Suzuki et al. Table 1 wherein the corn starch is replaced with a cyclodextrin mixture.

Suzuki et al. also teaches that the observed reduction in weight gain is due to the low digestibility of the α-cyclodextrin (see English translation of Suzuki et al., p. 5, lines 2-5).

> "... it was concluded that the body weight gain inhibitory effect and body weight reducing effect observed in rats treated with the commercially available cyclodextrin product were mainly due to the low digestion and availability of α-cyclodextrin."(page 5 lines 2-5)

Furthermore, Suzuki et al. demonstrates that their method suppresses weight gain only when about 18% of the total diet is replaced by α-cyclodextrin. See e.g., Figure 5 of Suzuki et al. (TAB E) and Figure 4 (TAB F) in the corresponding Suzuki and Sato journal article (*J. Nutri. Sci. Vitaminol.*, 31:209-223 (1985) already of record, "Suzuki and Sato"). Suzuki and Sato report that significant suppression of weight gain was only achieved in the rats fed the CD-30 and CD-40 diets, which comprise respectively about 18% and about 24% α-cyclodextrin. Suzuki et al. also teaches that for weight reduction the percentage of α-cyclodextrin in the diet should be preferably 20% and more preferably at least 20-30% of the total diet.

> To achieve the objective of the present invention, α-cyclodextrin (and α-cyclodextrin for the composition with α-cyclodextrin as the major component) should be used at 10% or more. For body weight gain suppression and body weight reduction, preferably it should be used at 20% or more, even more preferably used in the range of 20-30%. (page 7 lines 1-5)

Thus Suzuki et al. teaches adding α-cyclodextrin as a percentage of the total food intake regardless of the food's composition to suppress weight gain or achieve weight loss.

In contrast to Suzuki et al's instruction that the diets should comprise preferably 20-30% α-cyclodextrin to suppress weight gain or produce weight loss, Applicants' method suppresses weight gain with much less α-cyclodextrin. Applicants' test animals consuming a high fat diet comprising α-cyclodextrin and fat at a ratio of 1:10 display a significant reduction in weight gain even though only 4% of their total diet was α-cyclodextrin (specification Figure 3 and TAB D).

Suzuki et al. fails to teach or suggest a method wherein the amount of fat in a food product is determined and based on that determination α-cyclodextrin is added to the food product to achieve particular ratios of α-cyclodextrin to fat. Moreover, because Suzuki et al. fails to teach, suggest or even appreciate that α-cyclodextrin interacts in any way with fat, Suzuki et al. would not motivate one of skill in the art to develop a method such as applicants' claimed method.

In summary, Suzuki et al. does not teach, suggest or appreciate that α-cyclodextrin forms complexes with fat or that the complexes are resistant to lipase digestion. As such, Suzuki et al. does not teach or suggest applicants' claimed method and one of skill in the art based on the teachings of Suzuki et al. would not be motivated to determine the amount of fat in a food and then based on that fat amount add a sufficient amount of α-cyclodextrin, to achieve the ratios of α-cyclodextrin to fat of about 1:20 to 1:3 as taught by applicants. Nor would one of skill in the art have expected that applicants' methods would promote weight loss, reduce weight gain or maintain weight in a subject in need thereof because Suzuki et al.'s examples demonstrate

suppression of weight gain only when the α-cyclodextrin was 18% of the total diet and because Suzuki et al. teaches those of skill in the art to consume diets comprising preferably 20% and more preferably 20-30% α-cyclodextrin to suppress weight gain. Applicants examples use at most 4% α-cyclodextrin and obtained significant suppression of weight gain. Both the motivation to develop the claimed method and the expectation that the claimed method would successfully produce the desired results must be found in the cited art to support a rejection under 35 U.S.C. 103 (*In re Vaeck*, 20 USPQ2d 1438, 1442 (CAFC 1991)). Suzuki et al. fails to provide both the motivation and the expectation of success required by 35 U.S.C. 103 . As such Suzuki et al. fails to render applicants' claimed methods obvious.

In view of the foregoing amendments and remarks, applicants respectfully request that the Examiner reconsider and withdraw the rejection of the claims under 35 U.S.C. § 103.

OBJECTIONS TO THE DRAWINGS

The drawings are objected to for purportedly failing to comply with 37 C.F.R. 1.84 as set forth in the copy of Patent Drawing Review. In particular the Patent Drawing Review indicates that the top margins of Figures 9A-9C are not acceptable and the lines numbers, letters of Figures 9A-9C are not uniform clean and well defined. Applicants have submitted concurrently herewith replacement Figures 9A-9C that comply with 37 C.F.R. 1.84.

OTHER ISSUES

The Examiner raised other issues, i.e., that seafood and fish sticks are generally not considered as a meat product, it is unclear what makes up the deli slices, and that french fries and nut butters are listed as vegetables but generally these food items are not listed as vegetables. However, as discussed with the Examiner during the interview and upon her further consideration, the Examiner considers these issues resolved.

The Examiner states, referring to claims 91-94, "it appears that the α-cyclodextrin is consumed before a meal or is taken with the meal" and suggests amending the claims to recite

"consumed before a meal or with the meal." Although applicants do not believe that claims 91-94 are unclear, in the interest of expediting prosecution applicants have amended claims 91-94 to recite "is consumed by a subject before a meal comprising a fat-containing food product or with a meal comprising a fat-containing food product."

Applicants believe that this application is now in condition for allowance and request that the Examiner pass the application to issue. If the Examiner requires any additional information or clarification the Examiner is cordially invited to contact the undersigned.

Applicant believes no fee is due with this response. However, if a fee is due, the Commissioner is hereby authorized to deduct any missing or deficient fees from Deposit Account No. 06-2375, under Order No. AJC 201.1/10304772 from which the undersigned is authorized to draw.

Dated: Oct. 28, 2004

Respectfully submitted,

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AMENDMENTS TO THE DRAWINGS

Applicants provide herewith replacement sheets of Figures 9A, 9B and 9C.